UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JODI ROUVIERE and ANDRE ROUVIERE,	)	
Plaintiffs,	)	
v.	)	Case No. 1:18-cv-04814-LJL-SDA
DEPUY ORTHOPAEDICS, INC. n/k/a MEDICAL DEVICE BUSINESS SERVICES, INC. and HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS,	)	
Defendants.	)	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEPUY ORTHOPEDICS, INC.'S MOTION FOR SUMMARY JUDGMENT

Plaintiffs Jodi Rouviere and Andre Rouviere submit this Memorandum of Law in opposition to Defendant Depuy Orthopedics Inc.'s ("Defendant" or "DePuy") motion for summary judgment pursuant to Federal Rule of Civil Procedure 56. Plaintiffs submit each of the material facts raised in their amended complaint is in dispute by the evidence developed thus far warranting this Court to deny DePuy's motion for summary judgment and direct the case to proceed to trial by jury against DePuy.

I. INTRODUCTION.

On October 19, 2018, Plaintiffs filed an amended complaint ("complaint"), alleging Jodi Rouviere was implanted with the Defendant Depuy's "Summit" total hip arthroplasty system ("Summit Tapered Hip System Stem and Biolox Head") and Defendant Stryker MDM X3" ADM/MDM System and Trident Shell, "The Restoration," which was defective causing "severe

and permanent personal injuries including elevated blood levels of chromium, chromium toxicity, elevated blood levels of cobalt, cobalt toxicity, titanium, titanium toxicity, inflammation, pain, swelling, loss of range of motion, surgical removal and revision of hip replacement system, hip explant, pain and suffering, economic loss, and permanent disability." *DE# 26, p.1.*

The complaint further alleges DePuy was aware of adverse reports to the FDA of widespread failures of ADM X3 System and Trident shell, "The Restoration" and ADM/MDM System. Id., p.3___. DePuy designed, developed, tested, manufactured, assembled, promoted, labeled, packaged, advertised, marketed, distributed and sold the Summit Tapered Hip System stem and Biolox head to surgeons and hospitals. Id., p.10;

DePuy knew that Jodi Rouviere's surgeon Dr. Robert Buly would mix and match components of various hip systems with other hip systems. DePuy failed to provide adequate warning and/or supervision of surgeons implanting these hip components. Id. p.12. DePuy owed a duty to Plaintiffs and Dr. Buly "that its product would be implanted in a medically safe manner including the use of all its own hip system parts." Id.

DePuy marketed and promoted the Summit System's stem and Biolox head directly to Plaintiffs as: (1) "uniquely designed to meet the demands of active patients like you and help reduce pain."; (2) the best surgical option that "recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."; and (3) "99.9% of Summit hip components are still in use today." However, DePuy did not disclose to Plaintiffs when making such marketing and promotional presentations that: (1) "[o]ver 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failure or complications of the Summit Devices."; and (2) Summit Devices may result in metallosis, biologic toxicity and high failure

rate; (3) when implanted, the Summit Device "results unsafe release of toxic metal particles and ions into hip implant recipients' tissue and bloodstream" causing tissue death and bone erosion; (4) DePuy conducted no clinical trials of the Summit Device and Biolox head before marketing and selling it to surgeons and hospitals and Plaintiffs; DePuy knew the Summit Tapered Hip System stem and Biolox head posed an unreasonably high risk of causing metallosis, biologic toxicity, and total hip failure. *Id. pp. 13-14, 17.*

In the absence of such critical information as to the consequences of being implanted with the DePuy and Stryker Devices, Plaintiffs reasonably relying on DePuy's representation sought out the surgical expertise of Dr. Buly. (*Ex. Buly 74*). Dr. Buly examined Plaintiff Jodi Rouviere and determined that a hip implant was medically appropriate. Dr. Buly told Plaintiff: "If she is completely disabled by the pain, she really would like to go with a replacement. The risks and benefits were discussed with the patient. We may have to use a constrained implant like the Biomet Freedom, a modular dual mobility device by Stryker, which allows a bigger head and more stability. In fact, after her last arthroscopic surgery, her surgeon said that with the arthritis changes that are present in the hip, he feels that she is going to need a replacement as well." (*Exhibit: Buly 74, p. 59*). Based on the information Dr. Buly provided to Plaintiffs and the representations made by DePuy, Plaintiffs agreed and consented to the hip system implant. Mrs. Rouviere was told by Dr. Buly that the ceramic head (Biolox) and polyethylene liner would be articulating in her hip implant construct and that this would mitigate the risk of metal toxicity or metallosis. But this is not what happened, instead the Stryker MDM chromium cobalt liner insert and the DePuy Summit Stem impinged on one another causing high levels of metal wear and ions, metallosis and necrotic hip tissue. These large amounts of metal debris and ions were distributed throughout Mrs. Rouviere's system that imposed multiple negative effects on Mrs.

Rouviere's body and health. ["Jodi Dep."77:1-77:6, 78:1-78:9, 299:14-299:23] Dr. Buly told Mrs. Rouviere he would be implanting a safe option to metal-on metal so she did not need to be concerned with the risks metal-on-metal had presented in the past which she had concerns about (toxic poisoning and metallosis). *[Jodi Dep." 291:18-291:22, Def Exhibit 74, P 60*]. DePuy denied advertising and establishing the Summit stem (and Biolox Head) is good for and can help soft-tissue laxity *["Camino Dep." 118:11- 118:18]* but then DePuy contradicted themselves when they testified the Summit Stem "helps surgeons manage soft-tissue laxity intraoperatively" *[Camino Dep." 125:05-125:22, 126:21-126:24]*. DePuy testified that no warning existed in DePuy's IFU for the Summit Stem and Biolox Head placed into Mrs. Rouviere that the products were contraindicated to use in a person with soft-tissue laxity *[Camino Dep." 117:4-117:14]*.

On August 14, 2012, Dr. Buly implanted a DePuy Summit Tapered Hip System Stem and Biolox head and a Stryker ADM/MDM X3 liner/insert and Trident shell into Plaintiff's right hip (*Ex. Buly 74, p.244*) which consisted of the following femoral components: "the femoral stem was the Depuy Summit stem un cemented stem size #1 high offset 125mm component; the head was a Depuy Biolox delta art cam HD 28+5 mm", along with the acetabular components: Stryker MDM *(liner)* and "Stryker acetabular shell HA cluster hemi 52mm (Trident) ; Stryker ADM X3 28/48 polyethylene insert. " *[Source: Operative Report of Index Surgery, Ex. Buly 74, p. 244*] Although Dr. Buly adhered to the instructions, directions and other information provided by DePuy, Ms. Rouviere's Summit Tapered Hip System stem and Biolox head and Stryker MDM System/ADM X3 and Trident shell failed. By the end of 2012, she experienced pain and loss of range of motion. *Id. 23 (Ex. Buly 74, P 40)*. Unaware of the increased dangers of impingement of metal components and increased metal wear and ions to which the patient was exposed from the ceramic on polyethylene construct, Dr. Buly's post operative care did not medically take into

consideration nor address the possibility of Plaintiff's heightened exposure to dangerous metal wear debris and ions. Explaining whether he follows up with a treatment protocol based on potential metal wear exposures post operatively in patients with ceramic-on-polyethylene constructs, like he does when patients with metal-on-metal constructs, Dr. Buly testified "No. Ceramic-on-polyethylene would not generate the cobalt or chrome ions." *["Buly Dep" 218:14-219:7]* Dr. Buly testified that other than some people that have a known allergy to nickel, he was not aware of other problems with metal *["Buly Dep." 252:8-252:10]*.

Dr. Buly testified his knowledge about metallosis is limited to metal-on-metal hip implants and that the sales representative for DePuy has never told him anything about it ["Buly Dep." 161:20-164:02]. Dr. Buly did not expect the MDM and the Summit Stem to impinge. It's *(The MDM)* an implant we use when we try to minimize any chance of impingement. In other words, I feel that it's the best one that's currently available to minimize impingement. ["Buly Dep." 302:23-303:2]

On November 11, 2016, Mrs. Rouviere underwent revision surgery. The diagnosis given by Dr. Carlos Alvarado, MD was "Failed R THA due to trunnionosis and metal debris". [Ex. 20 P 60] DePuy's Summit Tapered Hip System stem visibly deteriorated, released and releases metal particles, including hydroxyapatite and other coatings and textures, from its surface into Mrs. Rouviere's blood, internal organs and muscle tissue. [redacted] Metals cobalt, chromium, titanium, aluminum and other metals from the DePuy and Stryker hip components were present in Mrs Rouviere blood and kidney stones. [redacted] *P54-58), Alvarado 68, Alvarado 48 p. 162*)

Dr. Buly would not have selected the Summit Tapered Hip System's stem and Biolox head with Stryker's ADMX3/MDM System and Trident shell had he known that its usage under

normal, ordinary and foreseeable conditions would result in its impingement and higher than normal wear causing increased release of titanium, vanadium, aluminum, and other metals and metal ions into Mrs. Rouviere's body. **ii. Deposition Dr. Robert Buly** CITATION. Id. 30.

Plaintiffs claim negligence, negligence per se (first claim for relief), negligent failure to warn, strict product liability (second claim for relief) and failure to warn, and breach of express warranty (third claim for relief) and breach of implied warranties (fourth claim for relief) against DePuy. Plaintiff Andre Rouviere asserts a claim of loss of consortium against DePuy.

II. PLAINTIFF'S EVIDENCE IN SUPPORT OF THEIR CLAIMS FOR RELIEF.

The Plaintiffs developed the following evidence in support of each of their claims for relief:

Deposition Dr. Robert Buly: Dr. Buly testified he was not aware and no one ever informed him that the Summit Duofix HA stem and Biolox head could not be compatible with the Stryker ADM/MDM X3 and Trident cup [Buly Dep. 224:13- 224:23] and that no one has ever told him that the specific products placed into Mrs. Rouviere manufactured by Stryker and the specific products placed into Mrs. Rouviere manufactured by DePuy were not compatible [Buly Dep. 226:8-18].

Dr. Buly further testified to the following:

> "Any surgical procedure has risks, and you have to weigh the risks with the benefits and make sure that the patient is aware of any potential risk going into surgery." ["Buly Dep." 34:17-34:22]
>
> Dr. Buly testified metal debris can occur from impingement, the body reacts from it, and it can cause metallosis and unusual synovium ["Buly Dep." 31:20-31:23, 32:23-32:25, 250:8-250:11] but then Dr. Buly testified his knowledge about metallosis is limited to metal-on-metal hip implants and that the sales representative for DePuy has never told him anything about it ["Buly Dep." 161:20-164:02].

Dr. Buly testified that a metal-on-metal bearing would have even less range of motion than the MDM did and would be even more likely to impinge. [“Buly Dep.” 140:2-140:7]

Dr. Buly’s indicated that to his knowledge there is no risk of metal to metal component impingement or resulting exposure to dangerous metal wear debris with the ceramic-on-polyethylene construct when he testified that he does not concern himself with dangerous metal debris for patients with a ceramic-on-polyethylene construct because “In a metal-on-metal, yes. We know that ions can be detected in the body**.** Without a cobalt chrome head, I'm not aware that ions are detected in the body to any degree.” [“Buly Dep.” 219:21-220:17]

Dr. Buly does not ever refer to “component impingement” in his office notes nor in his own definition of “impingement”. Dr. Buly testified the definition of impingement is “when the anatomy is abnormal due to the socket or the femur and the range of motion is not normal” which refers to impingement involving one’s natural anatomy (anatomic impingement) and not to impingement between components, and certainly not impingement of two (2) or more metal components. [“Buly Dep.” 13:21-14:01, Defs. Exhibit 8].

Dr. Buly initially proposed to Mrs. Rouviere the possibility of performing “something like a surgical dislocation to get rid of impingement” of her natural anatomy [Defs. Exhibit 8, P 3].

Mr. and Mrs. Rouviere both testified that Dr. Buly did not ever warn about the risk of component impingement even when demonstrating and describing the hip components he intended to use in surgery, of which Dr. Buly testified he also had no independent recollection and only refers to his office notes for his testimony [“Buly Dep.” 133:24- 134:06, “Jodi Dep.” 109:6-113:10, Defs. Exhibit 8] [1]

Hip impingement, in relation to Mrs. Rouviere’s natural anatomy and not in relation to components, was discussed with Dr. Buly [Defs. Exhibit 8, P 2- 6].

Dr. Buly’s concern about Mrs. Rouviere’s hypermobility and hip replacement was the risk of “subluxation” or “dislocation”, but

component impingement was not discussed [“Buly Dep.” 86:2-86:9, “Jodi Dep.” 112:10-112:13, Defs. Exhibit 8, P 7]

Mrs. Rouviere’s understanding of “impingement” prior to her surgery also related to her natural anatomy and not to components [“Jodi Dep.” 106:1-106:6].

Once Dr. Buly suggested a hip replacement, no other discussions occurred regarding risk of “impingement”, neither “natural” nor “component” impingement [Defs. Exhibit 8, P 7-8]. Impingement was not discussed as a warning in relation to components and hip replacement. The only warning made by Dr. Buly in all of his office notes is “high risk for dislocation” [Defs. Exhibit 8, P 7, Defs. Exhibit 8].

Dr. Buly testified that he warned Mr. and Mrs. Rouviere about impingement and dislocation “because if the implant impinges, it may dislocate. It may force the head to come out.” [“Buly Dep.” 70:21-70:24] But then Dr. Buly contradicts himself and testifies that **he does not specifically recall** saying the term “impingement” to Mr. and Mrs. Rouviere, only discussing the type of implants he was considering using and that he **“would have”** said it and that he **“probably”** even **demonstrated** impingement when he **showed her some implants** [“Buly Dep.” 264:10-264:25]. This testimony regarding the demonstration of the components to Mrs. Rouviere then also directly conflicts with Dr. Buly’s testimony that he **doesn’t recall if he demonstrated components** to Mrs. Rouviere [“Buly Dep.” 66:07-66:12].

Dr. Buly testified he did not have an independent recollection of warnings he provided to Mr. and Mrs. Rouviere and was dependent on his office notes. Dr. Buly’s office notes only indicate “dislocation” was given as a warning, not “impingement”. [“Buly Dep.” 70:11-70:14, 262:2- 263:7, Defs. Exhibit 8]

Dr. Buly testified recalling discussions with patients who have Ehlers-Danlos needing more stable implants such as a constrained implant or the modular dual mobility implants and needing a larger femoral head that has more potential stability. But again, Dr. Buly does not mention

the term "impingement" when he described his discussions ["Buly Dep." 26:03-26:16].

Dr. Buly testified that he **can't recall** how detailed and specifically potential complications were discussed with Mrs. Rouviere prior to her 8-14-12 hip replacement surgery. ["Buly Dep." 75:12-75:19]

Dr. Buly testified he independently recalls warning the Rouvieres about an intraoperative, mid-surgical, potential complication from the IFU related to impingement during one of their consultations with Dr. Buly. [DEPUY_ROUVIERE_0000064, "Buly Dep." 82:23-84:01]

Dr. Buly testified he did have a specific recollection of Mrs. Rouviere's first visit ["Buly Dep." 119:12- 119:16]. But then he contradicted his testimony when he cannot recall, even after referring to his own notes, if Mrs. Rouviere was in a wheelchair, walking or using crutches. ["Buly Dep." 120:16-120:23]

Dr. Buly testified he was not aware that either DePuy or Stryker already knew that the ADM/MDM X3 would impinge, at all [Buly Dep 245:6-245:11, 246:1-246:10].

Dr. Buly testified he depended on the FDA's approval for proof of the safety and efficacy of the implants he used ["Buly Dep." 185:1-185:4, 199:7-199:11, 207:17-207:23, 301:8-301:12].

But DePuy's two products that were placed into Mrs. Rouviere, The Summit DuoFix femoral stem and the DePuy Ceramic Femoral Head, in fact, were either illegally cleared by the FDA, or have never even been cleared at all [DEPUY_ROUVIERE_0000002, DEPUY_ROUVIERE_0005073-DEPUY_ROUVIERE_0005085].

Dr. Buly testified that he was not aware that the Biolox head also contained chromium/chromium oxide ["Buly Depo" 128:16- 128:25, DEPUY_ROUVIERE_0003401-DEPUY_ROUVIERE_0003402].

Dr. Buly first testified the titanium alloy in the DePuy Summit Stem could be "chemically pure or it may have small amounts of other metals" ["Buly Dep." 125:1-125:12] and then he later testified the Summit Stem was a "titanium aluminum" stem, but he did not know it also contained

in its chemistry the metals vanadium and nickel ["Buly Dep."186:3-186:5].

Dr. Buly told Mrs. Rouviere the ceramic-on-polyethylene construct he was implanting was a safe option to metal-on metal so she did not need to be concerned with the risks metal-on-metal had presented in the past (toxic poisoning and metallosis) ["Jodi Dep." 291:18-291:22, "Buly Dep." 220:13-220:17, 230:14-230:15, Def Exhibit 74 P60]

Mrs. Rouviere was told by Dr. Buly that the head (Biolox) and liner (polyethylene) would be articulating in her hip implant construct and that this would mitigate the risk of metal toxicity or metallosis. But this is not what happened, instead the Stryker MDM chromium cobalt insert impinged upon the DePuy Summit Stem causing high levels of metal wear and ions, metallosis, necrotic hip tissue which caused large amounts of metal debris and ions and systemic distribution of them imposing multiple negative effects to Mrs. Rouviere's body and health ["Jodi Dep."77:1-77:6, 78:1-78:9, 299:14-299:23, "Buly Dep." 230:14-230:15]

DePuy did not advise surgeons, their customer, that they did not have proper approval to pair the DePuy Summit Duofix Hip Prosthesis with the DePuy Biolox Ceramic Femoral Head in August of 2012 ["Posner Dep." 40:12-40:19, 41:7- 42:11, "Buly Dep." 185:1-185:4, 199:7-199:11, 199:21-200:8, 207:17-207:23, 214:16- 215:13]

Dr. Buly testified that other than some people that have a known allergy to nickel, he was not aware of other problems with metal ["Buly Dep." 252:8-252:10].

iii. <u>Deposition of Dr. Alvarado:</u> Dr. Alvarado testified titanium debris causes black staining of surrounding tissues, indicating damaged tissue and an issue with the implant. Titanium can cause damage and toxicity to local tissue if wear debris is "severe" ["Alvarado Depo" 30:25-31:19]. Dr. Alvarado diagnosed Mrs. Rouviere with metallosis in both November 11, 2016 and February 17, 2017 revision surgeries related to both Stryker's acetabular and Depuy's femoral components [Defs Ex. 22, Defs Ex. 24].

iv. Deposition Corporate Representative DePuy Thomas Camino: Mr. Camino testified DePuy was aware that their products are used with other manufacturer's products ["Camino Dep." 45:13-47:18]. DePuy warned against using its components with those of other manufacturers and instructed surgeons not to do so, but argues it cannot prohibit the use of multiple manufacturers' parts entirely because surgeons practice medicine and treat their patients based on their knowledge, training, and experience. ["Camino Dep." 52:9-52:15]. DePuy's corporate representative testified that their instructions for use states not to utilize their components with competitive products (which is not what the IFU says), but that they do not prohibit it ["Camino Dep." 52:2-52:24, 57:5-57:9].

v. Deposition Sales Representative DePuy Leon Posner: Mr. Posner, DePuy's sales representative, testified that he "always" notifies any surgeons of DePuy's position that their products should not be mixed with those of other manufacturers and that surgeons "know" they have heard that from him. ["Posner Dep." 24:11-25:3]. DePuy sales representative testified he "absolutely" warns any surgeons he works with "of any dangers that could arise from what they are doing" ["Posner Dep." 25:17-25:19] but that he had no knowledge of any concerns related to the Stryker ADM/MDM X3 and/or Trident shell nor that they were inclined to impinge (on the stem) ["Posner Dep." 27:13-27:25]. DePuy's sales representative then contradicts himself and testifies that he does not question nor correct surgeons for fear he will lose his job ["Posner Depo" 30:18-30:24]. He lets "all" surgeons know the instructions for use and anyone who works in his business is aware different products are used in different procedures quite often. ["Posner Depo" 20:15-20:18] He then testified that "anytime" something is used outside of "the appropriate way" it is his role to let surgeons know that this could be classified as an off-label use ["Posner Depo" 22:4-22:14]. He "absolutely" warns any surgeons he works with "of any

dangers that could arise from what they are doing" ["Posner Dep." 25:17-25:19] but that he had no knowledge of any concerns related to the Stryker ADM/MDM X3 and/or Trident shell nor that they were inclined to impinge (on the stem) ["Posner Dep." 27:13-27:25]. DePuy's sales representative then contradicted himself and testified that he does not question nor correct surgeons for fear he will lose his job ["Posner Depo" 30:18-30:24].

vi. <u>Deposition of Dr. Bobst (toxicologist):</u> Dr. Bobst testified to the following:

> "My opinion is that, to a reasonable degree of scientific certainty, they [cobalt, aluminum titanium, alloy] are a significant contributing factor to her conditions she experienced." ["Bobst Depo." 78:3-78:6]
>
> "My understanding of the metal debris could be including of everything that was inserted into Jodi Rouviere, and that was cobalt and chromium from the stem that was impinging -- I'm sorry -- on the liner that was impinging on the stem, and then the stem is a titanium alloy that includes titanium, nickel, aluminum, and vanadium." ["Bobst Dep." 48:13-48:19]
>
> Metal debris or metal is impacting local tissue, can include infiltration of cells from the immune system, like microphages, and affect the health of cells, including necrosis of them. ["Bobst Dep." 46:2-46:7]
>
> "My understanding is there was impingement on rubbing of the liner against the stem, which created a gouge and metal debris." ["Bobst Dep." 49:7-49:9]
>
> My understanding is two pieces of metal were 16 rubbing against each other and that caused debris to be released into tissue." ["Bobst Dep." 49:15-49:17]
>
> "There was a gouge in the stem, and then there was noted wear along the liner of the ball portion that it was hitting to. Both those places of contact had wear." ["Bobst Dep." 49:22-49:25]
>
> Significantly, the kidney stones contained the same metals as in the implants, another good indication of metals in her body, risk and biological indication those present in the kidney stones were likely forced from the metal hip implant ["Bobst Dep." 96:5-96:13].

If metals ionized and got into the circulatory system one way they would be excreted is through the urine; if normal kidney function isn't happening and stones form, stones can also pick up any metals in the body. ["Bobst Dep." 96:17- 96:22]

"During the period of time that Jodi Rouviere had the hip implant, including the stem and the liner in her body that was impinging and having corrosion, metal debris could have went into her body. That metal could have been hard metal or metal that was ionized over time. That metal can move around and stay in the body, and that debris could have stayed there for years as part of that process." ["Bobst Dep." 57:9-57:17]

She had a cobalt and chromium liner and a titanium alloy; the alloy has nickel, aluminum, and vanadium. ["Bobst Dep." 57:21-57:24]
"These things in their body have known toxicological properties, including neurological symptoms that have been reported in the literature in implant." ["Bobst Dep." 58:1-58:4]

She had exposure, dose – and over time -- a serum or plasma *(level)* is saying what we are seeing that's part of what's in her body or circulating. An increase is saying there's still exposure or dose or metal in her body, that can last for a period of time until it's completely gone or there's debris. I see a scientifically plausible explanation why it's going up, and it's to a reasonable degree of scientific certainty I think that's what happened. ["Bobst Dep." 58:5-58:17]

Any cobalt that could have been released into her body up to that date and point could have been sourced from anything previously in her body to that time. ["Bobst Dep." 59:1-59:4]

So, from a toxicological perspective something foreign was put in her body; that it contained metals; that those metals were detected in both pathology and blood tests. SO that's over the course of that time. ["Bobst Dep." 63:22-64:1].

The test is an indication of her condition at that time. There are components in her body over those seven years that contain cobalt and chromium. Based on the cobalt for sure, with higher numbers over time,

I am to a reasonable degree of scientific certainty, that cobalt and chromium came from those metal implants [“Bobst Dep.” 64:2-64:19].

Both of those tests were within a reference range less than 0.2, but there's also .6. There's still a rise. Any change, biologically we have reference of is of interest for noting any changes [“Bobst Dep.” 64:22-65:2].

Any foreign medical device put into a body has potential hazard and risk to release material into the body through a variety of ways [“Bobst Dep.” 67:22-67:25]

My understanding in this case is that the impingement is what created a lot of metal debris. Something just naturally being there --from a toxicological stretch, it was normally outside the body -- could just be a plain source of releasing it into the body, but there's been impingement and release of metal debris, a major factor in this specific case. Normally, large amounts of cobalt and chromium and titanium alloy are not inside the body, but when they are put in, that can have an impact. [“Bobst Dep.” 68:1- 68:13]

Part of my work as a toxicologist includes understanding how FDA approves medical devices, including making sure they are safe [“Bobst Dep.” 70:19-70:22].

The idea of something being safe should be, if you put it in the body, it should not release toxins or be unsafe.[“Bobst Dep.” 70:22-70:24]

From a toxicology perspective, cobalt-chromium and titanium alloy components, including titanium, aluminum, nickel, vanadium, all have toxicological properties or hazards. Exposure is putting that into somebody's body. Hazard and exposure is part of risk; increasing risk when you have both. That increased risk, for toxicology outcomes, can be from just being there. Not just being there, being there and forming debris. Both those things can be part of that understanding of risk, hazard, exposure, being in the body, being in the body and having debris and impacting what gets into the body that's normally not there, and that includes these metals of -- [“Bobst Dep.” 71:6-72:1]

Any indication of rise in metals from something hazardous is a note of dose and exposure of something with known hazard. There is nothing normal about that [“Bobst Dep.” 72:21-72:25].

(Somebody with cobalt and chromium hip implants is likely to have levels above the reference range) That is not normal (*n)*or someone that understands toxicology when physicians make those statements. That is not a toxicological understanding. There is an increase because something foreign is put into the body with known toxicological hazards causing that. In toxicology, we talk about known hazards; dose and exposure; measurements. There's nothing normal for somebody that has that in their body, especially if they are also unfortunate to have debris or other symptoms, from a toxicological perspective of several metals that had those known hazards [“Bobst Dep.” 73:1-74:1].

(Clinical significance of cobalt levels of .9) Outside of what is considered normal reference range, as shown in the medical record. Clinical significance says there's something outside of normal biology adding metal in the body. In this case, the implants [“Bobst Dep.” 74:3-74:7].

(Clinical relations to the metals) Risk of tachycardia, concentration, cognitive functions, and reference to literature. Cognitive functions can include an area of being able to concentrate, nausea, some of her headaches; being alert and feeling good, normal, or understand her awareness and environment. For cobalt, neurotoxicity can include that symptom *(lack of concentration as a cognitive function)*. Titanium alloy, can have neurotoxic effects, especially aluminum [“Bobst Dep.” 74:21-75:1, 75:18-75:21, 77:4-77:7, 77:11-77:20].

To a reasonable degree of scientific certainty, they *(the metal debris or ions)* are a significant contributing factor to her conditions she experienced [“Bobst Dep.” 78:3-78:6].

"Risk of experiencing adverse immunological and neurological symptoms similar to her medical conditions." I guess I worded that a little differently in the report, but I would also say that it's a significant contributing factor. Increased the risk of experiencing those as to me, it's the increased risk, as I see it, as a significant contributing factor [“Bobst Dep.” 78:12-78:21].

I'm not comparing any *quantification* of that risk direct with human data because, fortunately, people don't do experiments with humans putting in toxic metals and measuring things. I can point to documented case reports of known exposure and effects in humans and neurologically in animals. ["Bobst Dep." 83:10-83:18].

The risk ties what we know in human and animal data. I didn't quantify it because there is no other data than when these bad things happen; to do so with other humans or experiments would be unethical. We have to work with what we have, literature and other experiments with animals or human cells or when we see reports ["Bobst Dep." 83:19-84:2].

A blood level or circulating number is not a direct impact of the quantifiable risk because that would assume what you see in blood is a direct representation of what you see in the body overall. That is not accurate or correct. It just says when we test blood medium as a system, it's one part of the body that metal can get into. That the metal ions that can circulate and not the metal that can be in a certain place ["Bobst Dep. 84:15-85:1].

Part of that comparison you're asking is if metal gets into the body from the implant, it can be stationary, not moving, not detecting, not releasing the ions. Studies are limited because of these issues. ["Bobst Dep." 85:2-85:9]

If it *(metal debris and metal ions)* ionizes and gets into circulation, it can be excreted, but if it's debris in its metal form that's not reacting, that can stay dormant and present for years or perhaps change immediately, and that can also slowly release and add to the levels ["Bobst Dep." 85:22-86:3].

It is possible, but not probable to a reasonable degree of scientific certainty to have the metal debris that Jodi Rouviere had, the levels she had, and still not cause the symptoms she complains of ["Bobst Dep." 86:6-86:14].

She had something foreign put in her body that had these metals; metals seen in pathology and blood and then other symptoms. That's risk. It's an outside dose from something that's not normally in the body. That part of

a dose with something you know is hazardous constitutes some risk, so that risk is part of an overall factor of what her condition is -- I didn't quantify that, the risk is there; I know it increased because it was there; and it's consistent with the symptoms that are in the reported literature from someone that has it. Quantitatively comparing blood levels is not a direct indication of how much the metal can be. A lot of it can stay for years. [“Bobst Dep.” 86:15-87:11]

Metal debris can be from titanium alloy and metal debris can be from wear that was on the liner. I don't know how much of each of that debris would be the debris in metal form in her body. I know the size of the gouge in the titanium alloy was the 7 mm by 4 mm. There was wear from the engineering analysis, on the cobalt-chromium liner. It happened qualitatively. I don't know how much qualitatively. Increased risk exists from cobalt, chromium and titanium alloy, which can include aluminum, nickel, and vanadium. Those have different toxicologic(*al*) and hazardous properties. These things with this metal, these components increase risk and can contribute and be consistent based on that understanding [“Bobst Dep.” 87:19-88:19].

Titanium alloy: Aluminum, nickel and vanadium can have neurotoxic effects [“Bobst Dep.” 90:1].

Removing an implant or metal product that was releasing debris or exposure can remove some of the source, but it doesn't remove all the source or exposure has ceased [“Bobst Dep.” 92:21-92:25].

I didn't do measure in blood and serum and any studies of comparison because it's not an indication of all possible exposure; dosing in the body [“Bobst Dep.” 102:19-102:25].

It's one measurement that can be done and people can, do, work with it, but it has limitations and it's meaningless. That's why I didn't do any of those comparisons or that work [“Bobst Dep.” 103:1-103:5].

It's relevant that it was elevated compared to a normal reference range. She had a foreign body source of cobalt, chromium, and others in her body and some of those metals were in kidney stones as well as in pathology. All of that is relevant [“Bobst Dep.” 103:10-103:16].

Blood is an attempt to look at something quantitatively, but unless you took the entire body and extracted it, which you can't do because that would end life, then you don't really have a direct answer. Blood is done partially, but it's indirect and not a direct quantitative possibility of everything that is there or could be there (elemental metal that isn't ionized and is not detectable and that could stay for a long time). Blood serum or plasma may not be indicative of that inert or inactive metal that could still be in the body [“Bobst Dep.” 105:6-105:19].

It's *(blood and serum testing)* not an objective or direct or accurate quantitative measure. You cannot measure that quantitatively without sacrificing somebody's life, which we, fortunately, don't do [“Bobst Dep.” 106:1-106:9].

She was at increased risk for metal toxicity in the symptoms exhibited that we know about it. There was metal debris and metallosis; other indications of metal in her body from kidney stones. She's an increased risk for metal toxicity because she had it put in her body, had evidence of metal debris, metallosis, et cetera, being released from that impingement or activity happening from 2012 to 2019. Those symptoms also are part of increased risk. That's a significant contributing factor to her case and condition because she had these put in her body for the intent of improving her hip. She had issues and other symptoms. In literature *(reference to)* when you see these other symptoms, detection in kidney stones, together with the story of evidence of exposure, increased risk, consistent with known symptoms, it is a significant contributing factor [“Bobst Dep.” 107:3-108:10].

I gave an overall qualitative consideration; There was not enough information qualitatively about exposure to put dose in [“Bobst Dep.” 109:9-109:12]. If I'm going to put a quantitative dose, I want to be confident in what that means. Exposure can include not just metal ions tested in the blood; blood does not test elemental metal that's still there and can be for seven *(several?)* years. [“Bobst Dep.”109:17-110:2] I didn't do a dose because I didn't believe I could come up with one or it wasn't important for the question of quantitatively increasing the risk. I did not calculate how much that risk is. [“Bobst Dep.” 110:3-110:6]. Sometimes toxicologists calculate it. I didn't do it here because it wasn't important for my opinion, I have to a reasonable degree of scientific certainty putting the metal implants in her; and impingement she

> experienced increased her risk with known toxicity of these metals, consistent with literature, I'm comfortable, to a reasonable degree of scientific certainty, that they contributed to her conditions. ["Bobst Dep." 110:9-110:20]
>
> Any outside form of cobalt, chromium, or anything from the titanium alloy not normally in the body either left or released contributed to increasing her risk. I don't have a quantitative answer. I didn't compare anything quantitative. I didn't see anything in the literature that made me comfortable to make quantitative doses. I could only do it qualitatively, and that's what I did. ["Bobst Dep." 114:11- 114:19].

vii. <u>Deposition Dr. J.W. Cohen Tervaert (immunologist):</u> Dr. Cohen testified "in Jodi's case, it's clear that there's metal debris that is taken up by the immune system." *Dep Cohen, p. 65:7-9.* He reviewed the report of the pathologist which Dr. Cohen found "extremely important in this case, because it proves the concept that [he] ha[s] put forward." *Id.* 68:1-4. Dr. Cohen determined "[i]t is more likely than not that Jodi Rouviere's exposure to excessive metal debris from the defendants' implanted hip components has caused her systematic symptoms such as those observed in autoimmune/autoinflammatory syndrome induced adjuvants ASIA. These injuries are permanent and render Jodi Rouviere highly susceptible to exacerbation of symptoms upon activation of the immune system when exposed to additional exposures in the future." *Id., p.107:9-18.* Dr. Cohen stated "[i]t's clear that there's metal debris detected, and she even had elevated levels of metals in the blood in the beginning. Her complaints started after the hip implant. So those are three major arguments why I think that indeed the metal debris is causative related to ASIA." Id., *108:10-15.* Dr. Cohen opined "it's more likely than not that the metal debris caused [metallosis] ." *Id., 111:8-14.*

viii. Deposition Dr. Francis Gannon (Pathologist): Metallosis and necrosis of the hip tissues that surrounded the Summit Duofix Stem in Mrs. Rouviere's hip were detected by Pathologist Dr. Frank Gannon in his expert report from the tissue that surrounded the Summit Duofix Stem removed intraoperatively by Dr. Alvarado in Mrs. Rouviere's 11-11-16 and 2-17-17 revision surgeries [Report (Gannon) FINAL, P1-13].

i. Declaration of Jodi Rouviere: Mrs Rouviere testified Dr. Buly never mentioned component impingement or the chances of it occurring in the hip implant he was to use in [her]." *Decl. Jodie Rouviere, p.1.* After Dr. Buly decided Mrs. Rouviere needed "a total hip arthroplasty, Dr. Buly never again mentioned the word 'impingement' to [her]." *Id*. Mrs. Rouviere stated that notations in the medical chart by Dr. Buly that she felt great was a false statement. Id. Mrs. Rouviere described the dislocation of her hip and subsequent examination by Dr. Alvarado. *Id., p.3*. After the hip surgery, her health gradually declined. She experienced tremendous pain and discomfort. Id., pp. 4-5. Mrs. Rouviere kept a detailed

ii. Declaration of Dr. Jarrell: Dr. Jarrell **"**was retained by the Law Offices of Andre A. Rouviere on or about October 28, 2020 to evaluate the explanted hip prosthesis systems manufactured by DePuy Orthopedics and Stryker Orthopedics and review documentation and data to determine if the components were defective in either their manufacture, design and/ or failure to adequately warn related to the above referenced matter." [CITATION]. He opined "the DePuy Summit femoral stem with Biolox head is defective due to the following defects which [he] ha[s] identified:

> 13. DePuy failed to warn specifically against pairing their DePuy Summit Duofix Hip Prosthesis and DePuy Biolox head with the Stryker Trident Acetabular cup. DePuy's

sales training documentation from 2009 shows their knowledge of the defective design issues with the Stryker Trident cup from the raised metal rim of the liner which causes metal contamination from femoral neck impingement with the Trident Cup. 2 DePuy educated their sales team on other manufacturer's dangerous and toxic failed components but did not warn against the pairing of their components with Stryker's failing product. 3

14. DePuy failed to warn that this neck impingement would result in the release of toxic metal particles and cytotoxic cobalt and chromium metal ions, when their internal documents demonstrate that they understood the risks of metal contamination from wear related to elevated metal debris and metal ions from cobalt chromium wear. 4

15. The DePuy IFU lacks sufficient Warnings. The IFUs that accompanied DePuy's Summit Stem and Biolox Delta ceramic head did not warn about expected metal to metal impingement and related potential for metal wear debris postoperatively. DePuy's Instructions for Use ("IFU") for the Summit Stem and Biolox Delta Head gave an interoperative warning about impingement and instructs the surgeon that range of motion should be thoroughly checked for improper mating, instability, or impingement and corrected as appropriate. However, they failed to warn or make other mention of expected metal to metal impingement and related wear debris in the DePuy Summit Stem and Biolox Head IFU 5,6

16. DePuy advertised that the Summit Stem's neck geometry decreased the risk of dislocation due to secondary prosthetic impingement in the Summit Tapered Hip System Surgical Technique. Additionally, DePuy advertised that the Summit Stem's design and polished neck decreased the risk of wear debris generation, secondary to prosthetic impingement in the 2011 Summit Tapered Hip System Surgical Technique. 7

17. DePuy has given warnings in the past when two products should not be paired together from a lack of compatibility, but failed to give such warnings against pairing their DePuy Summit Duofix Hip Prosthesis and DePuy Biolox head with the Stryker Trident Acetabular cup.

18. DePuy advertised that the Summit Stem's neck geometry decreased the risk of dislocation due to secondary prosthetic impingement in the Summit Tapered Hip System Surgical Technique. Additionally, DePuy advertised that the Summit Stem's design and polished neck decreased the risk of wear debris generation, secondary to prosthetic impingement in the 2011 Summit Tapered Hip System Surgical Technique.

19. DePuy's Instructions for Use (IFUs) did not contain adequate warnings of all known risks related to Ms. Rouviere's implants and injuries.

20. Ms. Rouviere had hyperlaxity as a pre-existing condition. A review of DePuy's IFUs and Surgical Techniques for the primary hip components showed that laxity and hyperlaxity was not contra-indicated for these components."

(Exhibits 80, pp 6 and 79 pp 24) .

C. Documentary Evidence

DePuy's IFU instructs surgeons to use only femoral components from the same manufacturer but does not give any warning related to the pairing of their femoral components (femoral stem and femoral head) with another manufacturer's acetabular components (Stryker ADM/MDM and Trident shell) [Defs. Exhibit 80, P 5].

The IFU that accompanied DePuy's Summit Stem and Biolox Delta ceramic head warned that "Implants and trial components from different manufacturers or implant systems should never be used together." [Defs. Exhibit 80, at DEPUY_ROUVIERE_00062]. This refers to the pairing of one manufacturers components with a different manufacturer's trial components. Trial components are used temporarily and intraoperatively in order to assess sizing in preparation for the permanent implant's placement. This warning does not refer to the pairing of two manufacturer's hip replacement components as in Mrs. Rouviere's case [Defs. Exhibit 80 at DEPUY_ROUVIERE_00062].

Mrs. Rouviere's hip replacement, like every hip replacement, required the combination of acetabular (Stryker) and femoral (Depuy) components to create the system. Without both the acetabular and femoral components, a hip replacement is not mechanically functional (Bates: DEPUY_ROUVIERE_0000001-DEPUY_ROUVIERE_0000024).

The Summit Stem and the Biolox Head were DePuy products implanted in Mrs. Rouviere and together they completed the femoral components of the total hip replacement she received [Bates: DEPUY_ROUVIERE_0000001-DEPUY_ROUVIERE_0000024].

The MDM Liner, ADM/MDM X3 Insert and the Trident Shell completed the acetabular components in Mrs. Rouviere [Ex: Buly PM 09]

Depuy's IFU refers only to using femoral components from the same manufacturer, a femoral head and a femoral stem, but does not give any warning about not pairing their components with another manufacturer's acetabular components (Stryker ADM/MDM and Trident shell) [Defs. Exhibit 80, P5].

The DePuy Summit Stem (and Biolox Head) Surgical Technique does not provide any warning on the utilization of their components with another manufacturer's [DEPUY_ROUVIERE_0000001-DEPUY_ROUVIERE_0000024].

Bobst report

Gannon Report

Dr. Alverado report • Dr. Alvarado spent over 45 minutes consulting with Mrs. Rouviere in his office on May 18, 2017 and noted her systemic decline, worsening pain and cobalt metal ions trending up from 0.6 to 0.9 ppb [Jodi Medical Record Complete2019 P319, P344]. Dr. Alvarado confirmed he may need to perform another surgical intervention and that a girdlestone would remove any chance of metal debris [Jodi Medical Record Complete2019, P345].
Mrs. Rouviere's blood cobalt levels had risen again and she was experiencing increasingly severe systemic and orthopedic symptoms. [Jodi Medical Record Complete2019, P319, P344, "Jodi Dep." 188:19-191:13]

III. DEFENDANT DEPUY'S MOTION FOR SUMMARY JUDGMENT

DePuy insists it is entitled to summary judgment in its favor and against Plaintiffs on each of the claims for relief presented in the complaint. Specifically, DePuy claims the following:

> 1. Rouvieres have failed to produce any reliable, competent expert testimony that any DePuy component was defective.
>
> 2. The Rouvieres' defective or inadequate warnings claims fail because: (i) DePuy warned of the specific harms that the Rouvieres allegedly experienced and therefore its warnings were adequate as a matter of New York law; (ii) DePuy's warnings cannot be the proximate cause of the Rouvieres' injuries; (iii) DePuy had no duty to warn about any alleged defects or risks in Stryker's components.
>
> 3. The Rouvieres' claims for breach of express warranty and breach of implied warranty of fitness for a particular use fail because neither warranty was created.
>
> 4. The Rouvieres' "claim" for loss of consortium is not a viable stand-alone cause of action.

IV. STANDARD OF REVIEW FOR MOTION FOR SUMMARY JUDGMENT

Summary judgment is warranted if the pleadings, admissible discovery materials and declarations setting forth statements that would themselves be admissible at trial (that is, not objectionable, such as hearsay, etc.), demonstrate that there is no genuine issue of fact necessitating trial. *Fed. R. Civ.P. 56(c)*; *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-323 (1986). A genuine fact issues exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Fincher v. Depository Trust & Clearing Corp*., 604 F.3d 712, 720 (2d Cir. 2010) (citing *Roe v. City of Waterbury*, 542 F.3d 31, 35 (2d Cir. 2008)). Where it is clear that no rational trier of fact could find in favor of the non-moving party, summary judgment is warranted. *Gallo v.*

Prudential Residential Servs., Ltd., 22 F.3d 1219, 1223 (2d Cir. 1994). Once a moving party has put forward facts showing that the non-movant's claims cannot be sustained, the opposing party must come forward with specific facts showing a genuine issue of material fact requiring trial. *Wright v. Goord*, 554 F.3d 255, 266 (2d Cir. 2009). Self-serving affidavits, sitting alone, are insufficient to create a triable issue of fact and defeat a motion for summary judgment. *BellSouth Telecommunc'ns Inc. v. W.R. Grace & Co.-Conn*., 77 F.3d 603,615 (2d Cir. 1996). In addition, parties may not defeat summary judgment on the basis of conclusory allegations or assertions; they must offer some hard evidence in support of such factual assertions. *See Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir, 2010); *Brink v. Union Carbide Corp*., 210 F.3d 354 (2d Cir. 2000) ("Rule 56 provides that any affidavits submitted in opposition to a properly supported motion for summary judgment 'shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein.")

Accordingly, the evidence proffered by the party opposing summary judgment must be of a type that would be admissible at trial. Id. ("Thus, 'hearsay testimony . . . that would not be admissible if testified to at ... trial may not properly be set forth in [a Rule 56] affidavit.'") (*citing Fed. R. Civ. P. 56(e)*; *H. Sand & Co. v. Airtemp Corp.*, 934 F.2d 450,454-55 (2d Cir.1991); *Burlington Coat Factory Warehouse Corp. v. Esprit De Corp*., 769 F.2d 919,924 (2d Cir.1985) (a party "cannot rely on inadmissible hearsay in opposing a motion for summary judgment ... absent a showing that admissible evidence will be available at trial.")). Ultimately, of course, a party must show that there is more than some metaphysical doubt as to the material facts. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986).

V. ARGUMENT

Plaintiffs submit there are genuine issues of material fact that are in genuine dispute and must be resolved at trial by a jury. Defendant DePuy is not entitled to summary judgment on any of Plaintiffs' claims for relief in their complaint. Thus, for the reasons presented below based on the evidence and material facts included herein, Plaintiffs respectfully submit this Court should deny DePuy's motion for summary judgment and direct this case to trial by jury on each of Plaintiff's claims for relief.

B. Plaintiffs' Negligence Claim

To state a claim for negligence under New York law, a plaintiff must show: "(1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) breach of that duty so that a product is rendered defective, i.e., reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or damage." *Santoro ex rel. Santoro v. Donnelly*, 340 F. Supp. 2d 464, 484 (S.D.N.Y. 2004) (*citing McCarthy v. Olin Corp*., 119 F.3d 148, 156 (2d Cir. 1997)). "Causation is an essential element of any negligence claim; if the plaintiff is unable to establish that [her] injuries were proximately caused by the defendant's conduct, summary judgment is proper." *Petitt v. Celebrity Cruises, Inc*., 153 F. Supp. 2d 240, 252 (S.D.N.Y. 2001); *see also Schipani v. McLeod*, 541 F.3d 158, 162-63 (2d Cir. 2008) ("In order for the defendant to be held liable, the plaintiff must show not only that the defendant was negligent, but also that `the defendant's negligence was a substantial cause of the events which produced the injury.'" (*quoting Derdiarian v. Felix Contracting Corp*., 414 N.E.2d 666 (N.Y. 1980))).

C. Plaintiffs' Strict Liability Claim

To state a claim for strict liability under New York law, a plaintiff must show: "(1) the product is `defective' because it is not reasonably safe as marketed; (2) the product was used for a normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff by the exercise of reasonable care would not have both discovered the defect and apprehended its danger; (5) the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care." *Fane v. Zimmer, Inc.*, 927 F.2d 124, 128 (2d Cir. 1991) (*quoting Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (App.Div. 4th Dep't 1979), aff'd, 417 N.E.2d 1002 (N.Y. 1980)); *see also Cosby v. City of White Plains, N.Y.*, No. 04 Civ. 5829, 2007 WL 853203, at *7 (S.D.N.Y Feb. 9, 2007). "[T]o establish a prima facie case, the plaintiff is required to show that the defectively designed product caused his injury and that the defect was the proximate cause of the injury." *Voss v. Black Decker Mfg. Co.*, 450 N.E.2d 204, 209 (N.Y. 1983); *see also Derienzo v. Trek Bicycle Corp.*, 376 F. Supp. 2d 537, 560 (S.D.N.Y. 2005); *Olsovi v. Salon DeBarney*, 500 N.Y.S.2d 325, 326 (App.Div. 2d Dep't 1986).

D. Plaintiffs' Failure To Warn Claim

1. Applicable Law

Under New York law, a plaintiff "may recover in strict products liability or negligence when a manufacturer fails to provide adequate warnings regarding the use of its product" (see, Voss v Black Decker Mfg. Co., 59 N.Y.2d 102, 106-107; Torrogrossa v Towmotor Co., 44 N.Y.2d 709; Wolfgruber v Upjohn Co., 72 A.D.2d 59, 62, affd 52 N.Y.2d 768). A manufacturer "has a duty to warn against latent dangers resulting from foreseeable uses of its products of which it knew or should have known" Liriano v Hobart Corp., 92 NY2d 232, 237 [1998]; see also Rogers v Sears,

Roebuck & Co., 268 AD2d 245 [1st Dept 2000]; Baum v Eco-Tec, Inc., 5 AD3d 842 [3d Dept 2004]. Although a product may "be reasonably safe when manufactured and sold and involve no then known risks of which warning need be given, risks thereafter revealed by user operation and brought to the attention of the manufacturer or vendor may impose upon one or both a duty to warn." Cover v Cohen, 61 NY2d 261, 275 [1984]. A manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics or economic necessity, is necessary to enable the manufacturer's product to function as intended." *Dummitt v. Crane Co.*, 27 N.Y.3d 765 (June 28, 2016); see also Rogers v Sears, Roebuck & Co., 268 AD2d 245 [1st Dept 2000]; Berkowitz v. A.C. and S, Inc., 288 A.D.2d 148 (N.Y. App. Div. 2001), Sawyer v. A.C. & S. Inc., 111152/99 (N.Y. Sup. Ct. June 24, 2011).

"To establish a claim for strict products liability under a theory of failure to warn, a plaintiff must prove that '(1) a manufacturer has a duty to warn[,] (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm.'" *Kennedy v. Covidien*, LP, 2019 WL 1429979, at *5 (S.D.N.Y. March 29, 2019) (*quoting Goldin v. Smith & Nephew, Inc.*, 2013 WL 1759575, at *5 (S.D.N.Y. Apr. 24, 2013)).

2. **The Adequacy of DePuy's "Warning" is a Question of Fact for the Jury.**

The "adequacy of a warning generally is a question of fact" best reserved for trial. Id. (quoting Kandt v. Taser Int'l, Inc., 2012 WL 2861583, at *3 (N.D.N.Y. July 10, 2012)) (emphasis in original). "Where a products liability claim is premised upon a failure to warn, a plaintiff may factually support his claims without utilizing expert testimony." Lara, 174 F. Supp. 3d at 744 (citing Billiar v. Minn. Mining & Mfg. Co., 623 F.2d 240, 247 (2d Cir. 1980) ("Under

New York law, the jury does not need expert testimony to find a warning inadequate, but may use its own judgment considering all the circumstances"); see also Sorto-Romero, 2007 WL 2816191, at *12 ("A jury may assess the adequacy of a warning, even in the absence of expert testimony").

Depuy relies upon the disqualification of Plaintiffs' initially expert, and argues that there its motion as if Plaintiffs have no engineering expert. As indicated above, Plaintiffs have timely retained and filed the Report of Dr. Jarrell, which should be considered by this Court in rendering its decision. However, Plaintiffs assert that the record evidence and facts referenced herein support Plaintiffs' failure to warn claims as an expert is not required.

Defendant Depuy knew that its Summit stem and head components, by necessity, had to be paired with another product, acetabular components, and that it would be paired with Stryker's ADM/MDM/X3 acetabular components. Depuy knew that the metal neck of its Summit stem would impinge with the metal liner if paired with Stryker's ADM/MDM/X3 acetabular components, particularly when implanted in a patient with pre-existing hyper flexibility. Depuy knew the metal (titanium alloy) neck of its Summit stem would grind on Stryker's metal (cobalt chromium) MDM liner during foreseeable use. Depuy knew that the grinding from this impingement would be longer in duration and subject to much harder force because the subject construct prevents dislocation. Depuy knew that the grinding of these metal components from such impingement would expose Plaintiff to dangerous exposures to toxic metal wear debris and the resulting metal ions.

Defendant Depuy claims it did warn and that its warnings were adequate as a matter of law. Depuy claims it warned of this exact risk: that the "component impingement" caused metal debris to be released. (SUMF 40,46). While this is not exactly the Plaintiffs' claim, Depuy

spends the next two (2) pages talking vaguely about its "IFU" and conspicuously avoiding the point. In fact, Depuy's Instructions for Use, the fine print pamphlet which is delivered with its product, mentions the word "impingement" once! (Exhibit 80 at p 8). This singular mention of the word "impingement" is in the "interoperative" section of the IFU, and simply instructs the surgeon to check the patient's range of motion during surgery for impingement that may exist during surgery.

Depuy testified that the only warnings it provided to surgeons are in Depuy's IFU or Surgical Technique inserts (Camino Depo 95:22; 57:8). Significantly, it is what the IFU does not inform or warn regarding its singular mention of the word "impingement" includes:

-- what type of impingement: "anatomical impingement" where some part comes into contact with the patient's anatomy; or "component impingement" where two (2) or more components come into contact with each other. Further, in a ceramic-on-polyethylene construct, like Plaintiff's, component impingement involve metal to metal contact, metal to poly contact, ceramic to poly contact, or something else.

-- The high likelihood known by Depuy that metal to metal impingement when paired with Stryker's ADM/MDM/X3 acetabular components.

--that the expected impingement would result in the grinding of the titanium alloy in the Summit stem against Stryker's cobalt chromium MDM would result in significant wear debris from Depuy's component.

-- Any other information regarding the high risk of metal to metal impingement, expected exposure to dangerous levels of metal wear debris, the need for post surgical monitoring and treatment or correction of the dangerous metal exposures anticipated by Depuy.

The "warning" Depuy relies upon in its IFU is not a warning at all, does not address the known likelihood of dangerous metal to metal impingement, particularly certain in the subject construct when implanted in a patient with pre-existing hyper flexibility, the expected high amounts of metal wear debris which will be created and deposited into Plaintiff, the dangers of the exposure to high levels of metals and the specific types of metals which would foreseeably be created from the expected impingement. The adequacy of a warning is generally a question of fact to be presented to a jury at trial, and in this case Defendant's "warning" does not address one (1) warning issue, specifically or otherwise, and therefore certainly is an issue for the jury.

3. DePuy's Failure to Warn is the proximate cause of Plaintiffs' injuries;

An inadequate warning is a proximate cause of the harm if it is a substantial cause of the events leading to the injury. *Sorto-Romero v. Delta Intern. Machinery Corp*., 2007 WL 2816191, at *11 (E.D.N.Y. Sept. 24, 2007) (*citing Belling v. Haugh's Pools, Ltd*., 511 N.Y.S.2d 732, 733 (N.Y. App. Div. 1987)). Defendant Depuy claims that there is no evidence that an adequate warning would have prevented Plaintiff's injuries, even assuming Depuy were to provide an appropriate warning regarding the dangers of which it was aware. This is simply not accurate.

First, Depuy argues that "Dr. Buly was already fully aware of the risk of component impingement in Mrs. Rouviere based on his own knowledge, skill and experience." Although Dr. Buly did testify that he was aware that metal to metal component impingement does present risks from the metal wear debris, Dr. Bully testified that he was not aware of the likelihood, even expectation that metal to metal component impingement was a risk in ceramic-on-polyethylene constructs, such as plaintiffs. In fact, Dr. Buly testified that he does not perform post operative metal testing on patients with ceramic-on-polyethylene constructs, like he does with metal-on-

metal constructs (with a chromium cobalt head), because he believes that "[n]o.Ceramic-on-polyethylene would not generate the cobalt or chrome ions. ["Buly Dep" 219:2, 219:6]. Further, Dr. Buly instructed Plaintiff pre-surgery that because hers is not a metal-on-metal construct, Mrs. Rouviere would not be exposed to metal wear debris from the articulation, but still mentions the possibility of anatomical impingement due to her hyper flexibility. ("Buly Dep." 308:25-309:12). Simply stated, Dr. Buly was not aware of the possibility of metal to metal impingement in a ceramic-on-polyethylene construct, and certainly was not aware of the high likelihood and expectation of dangerous metal to metal impingement when Depuy's Summit stem was paired with Stryker's ADM/MDM/X3 acetabular components.

Second, Depy asserts that Dr. Buly did not rely on the IFU that accompanied the Summit Stem and the Biolox Delta ceramic head when he selected the components. Depuy bases its claim solely upon the fact that "[a]lthough Dr. Buly testified that he had read the IFU at some point in the past, he did not recall the specifics of the warnings and instructions contained in it or reference the IFU during the August 2012 surgery. [SUMF ¶ 15.]" That anyone would not recall the specific warnings and instructions in a document from years before is not evidence that he would not have learned had the important information been provided. And notably, Dr. Buly did check Plaintiff's range of motion, intraoperatively, and confirmed that there was no impingement, as described in Depuy's IFU. Still, the singular mention of the word "impingement" in the IFU, in the context of checking the range of motion intraoperatively, is likely generally known to orthopedic surgeons, and would be conspicuously unremarkable. However, informing the surgeon of specific risks and dangers of the foreseeable use that the manufacturer is aware of -- such as, there is a significant risk of metal to metal impingement

between components in a ceramic-on-polyethylene construct, or that there is a high risk, even an expectation, that there will be metal to metal impingement when the Summit stem is paired with the Stryker ADM/MDM/X3, or simply do not pair the Summit stem with the ADM/MDM/X3 acetabular components, especially in hyper flexible patients -- would provide the surgeon with important, pertinent information regarding the risks, dangers and limitations of the products known by the manufacturer's.

Dr. Buly testified that he was aware of the importance of informed consent and that he personally met with Plaintiffs to discuss the risks and make sure the patient is aware of the risks before going into surgery. And the record evidence establishes that Dr. Buly did inform Plaintiff of the risks of which he was aware, such as informing Plaintiff that there are no risks of metal exposures from a ceramic-on-polyethylene construct like he planned to use, it also reveals that Dr. Buly was ignorant of the actual risks. Had Defendant, Depuy informed and warned surgeons including Dr. Buly of the risks and dangers of the foreseeable use of its products, he confirmed he would have made sure the patient, Ms. Rouviere, was aware of the risks before going into surgery. While Depuy argues that the surgeons rely upon their "knowledge skill and experience," it really hides behind their ignorance.[1] Had Plaintiffs known the risks of metal to metal impingement and resulting high exposures to metal wear debris and the resulting metal ions, they would not have authorized the surgery using the Depuy Summit stem with Stryker's

[1] Depuy asserts that it does not have a duty to "prohibit" pairing of its Summit stem with other manufacturer's acetabular components because surgeons are free to make their own decisions based upon their training and KNOWLEDGE (CITE: See bottom of page 6 top of page 7 in MSJ) Essentially, Depuy admits that it does not provide ALL of the information it has regarding defect and danger, instead promoting the surgeons to make decisions, inform the patients and to act upon their lack of knowledge or misinformation. However, there is evidence that Depuy does prohibit such use with other products (Declaration of John Jarrell)

ADM/MDM/X3 acetabular components. Plaintiff suffered injuries as a result of the exposure to metal wear debris from the Defendant's product. See Bobst, Gannon, opinions.

4. Depuy has a Duty to Warn of Defects, Risks and Dangers when Foreseeably Used with Stryker's Components,

Defendant Depuy claims that it has no duty to warn of the risks associated with a third-party's product, relying upon Rastelli v. Goodyear (1992). First it must be recognized that Plaintiffs' do not claim that Depuy has a duty to warn of potential risks (defects or dangers) of Stryker's product, as conveniently phrased by Defendant, but rather that Depuy has a duty to warn of the dangerous condition created in its own product when foreseeably used. Specifically, Depuy knew that its Summit femoral stem (with a metal neck) would likely impinge upon the metal liner of Stryker's component and cause substantial metal wear of its component, as well as the Stryker component, exposing Plaintiffs' to dangerous exposure to the resulting metal wear debris from its own product's intended, or unintended but foreseeable, use or operation. Depuy knew that its Summit stem components would be paired with Stryker's components (Deposition of Lee Posner 30: 17-34) .

In Rastelli, there were two (2) products, a tire and a multipiece rim. These products were made and distributed by two (2) different manufacturers and were placed together by a third party after sale. Although placed with or attached to each other, these products functioned independently of each other. As long as they fit together, there was no interaction, interrelation or synergy in the

operation of the combined product. This is also true of the asbestos case identified by the Defendants. *Dummit v. Crane, Inc., In Re New York City Asbestos Litig.* , ("NYCAL"), 59 N.E.3d 458 (N.Y. 2016). In either case it is important to note that in those cases the defendant manufacturers' products (the tire and the metal piston) were "sound," and the use or operation of its product did not cause or contribute to the failure or the harm. Furthermore, the other manufacturers' added products (the multipiece rim and asbestos) were clearly and admittedly defective and independently caused the damage upon exposure to those plaintiffs. The reasoning and application of Restalli and Dummitt specifically applies to the manufacturer of a "sound" product that has no synergistic involvement in causing or contributing to the failure or the harm. It is well-established that "[f]ailure-to-warn liability is intensely fact-specific." (Liriano v. Hobart Corporation). These cases do not apply to the manufacturer of a product that caused or contributed to the dangerous condition as a result of the foreseeable use and operation of that manufacturer's product, and is limited to the facts in the Rastelli case.[1]

The applicable law and analysis confirms that a manufacturer of a product does have a duty to warn of known dangerous conditions created from the foreseeable intended and unintended operation of its product, specifically including when such product was foreseeably and expectedly combined with another manufacturer's product after sale. Rogers v Sears, Roebuck & Co., 268 AD2d 245 [1st Dept 2000]; Berkowitz v. A.C. and S, Inc., 288 A.D.2d 148 (N.Y. App. Div. 2001), Sawyer v. A.C. & S. Inc., 111152/99 (N.Y. Sup. Ct. June 24, 2011). The Rogers Court considered the duty of the manufacturer of a gas barbecue to warn of the known dangerous conditions from necessarily combining its gas barbecue with the propane tank, despite it being manufactured and distributed by another. In distinguishing Rastelli, the Rogers Court specifically held that "Furthermore, even assuming the accident was caused by a defect in a

valve incorporated into a propane tank neither of which appellant manufactured, we are unpersuaded by appellant's argument that it was under no duty to warn of the dangers presented by such a defect, where its grill could not be used without the tank, and where its own warning to use the grill only outdoors was itself recognition of the danger of gas emission inherent in the use of the grill regardless of any defects." (Cite: Rogers at 246)

To apply the Rogers holding to the facts in the instant case: even assuming the *dangerous condition of metal to metal impingement* was caused by a defect in *Stryker's acetabular components*, which *Depuy* did not manufacture, *Depuy* is still under a duty to warn of the dangers presented by such a defect, where its *stem component* could not be used without the *acetabular components*, and where *Depuy's* own warning of the *dangers of impingement* was itself a recognition of the dangers inherent in the use of *Depuy's Summit stem* regardless of any defects. Depuy knew the dangers of metal to metal impingement from intended or unintended use or operation of its components (see IFU mention of "impingement"; other admissions/evidence of dangers of impingement). Depuy knew that its Summit stem would be paired with Stryker's ADM/MDM/X3 components. Depuy knew the metal neck of its Summit stem was likely to impinge when combined with Stryker's ADM/MDM/X3 components. Contrary to Depuy's representations that its stem components decreased the risk of dislocation and wear debris secondary to impingement, Depuy knew that its Summit stem would synergistically operate with the Stryker acetabular components, combining to create a dangerous condition exposing patients including Plaintiff to excessive metal wear debris. Accordingly, Depuy has a duty to warn of the known dangerous condition of such foreseeable and expected

use. Under these facts, like the facts of Rogers, the adequacy or reasonableness of Depuy's warnings is an issue of fact to be determined by a jury.

Further, assuming for the sake of argument that the Rastelli reasoning applied to the instant facts of the case at issue, Plaintiffs claim against Depuy is NOT based upon its failure to warn that Stryker's ADM/MDM/X3 components were or may have been defective, but upon the fact that Depuy knew that if its Summit stem was paired with the ADM/MDM/X3 component that it was highly likely that the metal neck of Depuy's Summit stem would impinge upon the metal (CoCr) MDM liner, creating a dangerous condition. This is not a situation that is analogous to the facts of the Rastelli case, where the other manufacturer's product catastrophically failed without any involvement or contribution by Firestone's tire. Nor is it analogous with the asbestos cases Defendant cites, where the asbestos is defective and poisonous upon user exposure without any synergistic involvement of the bare metal products to which the asbestos was attached after sale. In the instant case, Depuy knew its product would necessarily be combined with additional components (manufactured by a third party or otherwise) which was likely to impinge and create the dangerous condition in the foreseeable use or operation of Depuy's components, specifically including when paired with Stryker's ADM/MDM/X3 components. Furthermore, the Dummitt case, which Defendant tries to distinguish, specifically holds that"[T]he manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics or economic necessity, is necessary to enable the manufacturer's product to function as intended." (Dummitt at 463); see also Rogers v Sears,

Roebuck & Co., 268 AD2d 245 [1st Dept 2000]; Berkowitz v. A.C. and S, Inc., 288 A.D.2d 148 (N.Y. App. Div. 2001), Sawyer v. A.C. & S. Inc., 111152/99 (N.Y. Sup. Ct. June 24, 2011).[2]

The Dummitt Court confirmed that:

> "In deciding whether a manufacturer has a duty to warn certain users of its product about the hazards of using that product with another company's product, we must consider whether the manufacturer is in a superior position to know of and warn against those hazards, for in all failure-to-warn cases, this is a major determinant of the existence of the duty to warn (see Liriano, 92 N.Y.2d at 240–241, 677 N.Y.S.2d 764, 700 N.E.2d 303 ; Cover, 61 N.Y.2d at 274–277, 473 N.Y.S.2d 378, 461 N.E.2d 864 ; see also Rekab, Inc. v. Frank Hrubetz & Co., 261 Md. 141, 146–149, 274 A.2d 107, 110–112 [1971] ; Tibbetts v. Ford Motor Co., 4 Mass.App.Ct. 738, 741, 358 N.E.2d 460, 461–462 [1976] ; see also Restatement [Third] of Torts: Products Liability § 10 [b]; 63A Am. Jur. 2d, Products Liability § 1039). As we have previously recognized, '[c]ompared to purchasers and users of a product, a manufacturer is best placed to learn about post-sale defects or dangers discovered in use[,]... modifications made to or misuse of a product.'"(Liriano, 92 N.Y.2d at 240–241, 677 N.Y.S.2d 764, 700 N.E.2d 303). A manufacturer's superior ability to 'garner information' about *791 dangerous uses of its product extends to combined uses with other manufacturers' products (id. at 241, 677 N.Y.S.2d 764, 700 N.E.2d 303)." (Dummitt at 471-472).

> "Additionally, because the manufacturer's product is critical to the dangerous joint use of the two products, it does substantially create a defective condition insofar as both

> products combine to generate a defective and dangerous condition (cf. id. [relieving Goodyear from any duty to warn in part because its tire "did not create the alleged defect in the rim *795 that caused the rim to explode"]). Accordingly, we recognize a manufacturer's duty to warn of the peril of a known and foreseeable joint use of its product and another product that is necessary to allow the manufacturer's product to work as intended." (Dummit at 475)

Accordingly, even under the Rastelli line of reasoning, because Defendant Depuy knew that its Summit stem would be necessarily combined with acetabular components has a duty to warn regarding dangerous conditions created by the joint and synergistic use or operation of its stem components with such acetabular components, even if it did not manufacture the acetabular components.

Depuy has a duty to warn of the known dangerous condition of the foreseeable use or operation of its products. The cases cited by Depuy to argue that Stryker's acetabular components were the sole and exclusive cause of the subject impingement and creation of excessive metal wear debris do not support the avoidance of Depuy's duty to warn of known dangers from the foreseeable operation of its product. Whether Depuy complied with its duty to warn is a question of fact for the jury.

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[1] Significantly, the Dummitt case denied summary judgment in holding the Defendant manufacturer of a "sound" product does have a duty to warn of the peril of a known and

foreseeable joint use of its product and another product that is necessary to allow the manufacturer's product to work as intended." (Dummitt at 475, see discussion infra).

[2] The Dummitt concurring opinion specifically confirms this holding and the majority's refusal to further narrow the exception created:

> "I believe this test opens too broad an avenue of potential liability and that, in line with our precedent in this area, any standard must focus on the affirmative action taken by the manufacturer in placing the harmful product containing asbestos into the stream of commerce." (Dummitt at 483)
>
> "The risk of the majority's approach is further demonstrated by the jury charge in Dummitt, where the court instructed the jury, over Crane's objection, that "a manufacturer's duty to warn extends to known dangers or dangers which should have been known in the exercise of reasonable care of the uses of the manufacturer's product with the product of another manufacturer if such use was reasonably foreseeable" (majority op. at 782, 37 N.Y.S.3d at 730, 59 N.E.3d at 465). This is the " 'mere foreseeability' " test rejected by many courts considering the duty to warn . . . I would hold that, at a minimum, some action by the manufacturer in originally marketing the product with asbestos and promoting or recommending asbestos-containing replacement parts is necessary to impose a duty to warn." (Dummitt at 484)

Failure to Warn

Pure titanium has an element symbol of "Ti". The summit stem is not made out of pure titanium it is made out of a titanium alloy identified as Ti6AL4V. Depuys failure to properly label its Summit stem and advise its doctors of its true chemical make-up is a failure to warn. Dr. Buly was unaware of the toxic metals that exist in the Summit stem and testified under oath that he would in fact have still put it in Mrs Rouviere had he known of the toxic metals. However Dr. Buy did not testify that he would not at least first have warned Mrs. Rouviere that this Summit stem has those toxic metals in it. Depuys failure to fully advise and warn Dr. Buly of the chemical make-up of the Summit stem create a failure to warn. Dr. Buly could never have passed on this information or warned Mrs. Rouviere because he was unaware himself.

Mrs Rouviere who has already said in deposition that if she was aware of the toxic metals that were being placed in her body she would not of had the surgery. Depuys failure to advise doctors of the true chemical make-up of their titanium stem also leads to a failure of the medical community to properly diagnose a patient suffering from metallosis because they are led to believe that the Summit dual fix stem was pure titanium.

"[T]he manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics or economic necessity, is necessary to enable the manufacturer's product to function as intended." *Dummitt v. Crane Co.*, 27 N.Y.3d 765 (June 28, 2016)

D. Plaintiffs' Breach of Express Warranty Claims

A prima facie claim for breach of express warranty requires the plaintiff to "show that there was an 'affirmation of fact or promise by the seller, the natural tendency of which [was] to

induce the buyer to purchase' and that the warranty was relied upon to the plaintiff's detriment." *Tyler v. Kawaguchi, Inc.*, No. 00 Civ. 6366, 2006 WL 581184, at *5 (W.D.N.Y. March 8, 2006) (*quoting Friedman v. Medtronic, Inc.*, 345 N.Y.S.2d 637, 643 (App. Div. 2d Dep't 1973)). When a plaintiff brings a claim for breach of express warranty premised upon an allegation that a product was defective, it is the plaintiff's burden to establish causation. *See, e.g.,Beckford v. Pantresse, Inc.*, 858 N.Y.S.2d 794, 795 (App.Div. 2d Dep't 2008) ("Whether the action is pleaded in strict products liability, breach of warranty, or negligence, the consumer has the burden of showing that a defect in the product was a substantial factor in causing the injury."); *Bloomer v. Empire Forklift, Inc.*, No. 04-3182, 2007 WL 5613616, at *2 (N.Y.Sup.Ct. Ulster Cty. Feb. 26, 2007) (slip copy) (stating that plaintiff's cause of action for breach of express warranty must be dismissed "for the plaintiff's failure to establish any causal connection between the . . . incident and his alleged back injuries"), *aff'd*, 850 N.Y.S.2d 224 (App.Div. 3d Dep't 2007).

E. Plaintiffs' Breach of Express Warranty Claims

A prima facie claim for breach of implied warranty "requires that the plaintiff prove that the product is not 'fit for the ordinary purposes for which such goods are used.'" *Macaluso v. Herman Miller, Inc.*, No. 01 Civ. 11496, 2005 WL 563169, at *4 (S.D.N.Y. March 10, 2005) (citing Denny v. Ford Motor Co., 662 N.E.2d 730, 736 (N.Y. 1995); *Robinson v. Reed-Prentice Div.*, 403 N.E.2d 440, 443 (N.Y. 1980)). As is the case with a claim for breach of express warranty, a claim for breach of implied warranty requires the plaintiff to establish causation. *See, e.g.,Clarke v. Helene Curtis, Inc.*, 742 N.Y.S.2d 325, 327 (App.Div. 2d Dep't 2002) ("The defendant established its prima facie entitlement to summary judgment by demonstrating that there was no causal relationship between its product and the plaintiff's disease, an essential

element of the cause of action to recover damages for breach of implied warranty.") (citations omitted)); *Finkelstein v. Chevron Chem. Co.*, 60 A.D.2d 640, 400 N.Y.S.2d 548, 549 (App.Div. 2d Dep't 1977); *see also Derienzo*, 376 F. Supp. 2d at 551.

F. EXPERT OPINION EVIDENCE NECESSARY TO DEMONSTRATE CAUSATION

"Expert medical opinion evidence is usually required to show the cause of an injury or disease because the medical effect on the human system of the infliction of injuries is generally not within the sphere of the common knowledge of the lay person." *Barnes v. Anderson*, 202 F.3d 150, 159 (2d Cir. 1999) (*quoting Shegog v. Zabrecky*, 654 A.2d 771, 776 (Conn.App. 1995)); *see also Fane*, 927 F.2d at 131 (holding that New York law required expert medical testimony to attribute a bone fracture to the breakdown of hip implant in order to establish proximate causation on a negligent failure to warn claim); *Gold v. Dalkon Shield Claimants Trust*, No. B-82-383, 1998 WL 351456, at *3 (D. Conn. June 15, 1998) ("Medical evidence relating to causes of injury to the human body is not normally considered to dwell within the common knowledge of a layperson."), *aff'd*, No. 98-9346, 1999 WL 627689 (2d Cir. 1999).

G. *Plaintiff's Loss of Consortium Claim Remains Valid*

Because Plaintiffs' claims for relief withstand a summary judgment challenge at this stage of the proceedings in the instant case, Plaintiff Andre Rouviere's derivative claim for loss of consortium must stand.

[1] Defendants have consistently numbered their exhibits in depositions 1-91 and made reference to same in its Statement of Undisputed Material Facts (ECF# ___). Thus, Plaintiffs use the same reference "Defs. Exhibit" herein.

Respectfully Submitted,

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The undersigned certifies that the foregoing document was electronically served on the following counsel of record via e-mail on this 23th day of November, 2020.

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